K011189

Acueity, Inc JUL 1 6 2001

Summary of Safety and Effectiveness

Trade Name:

ViaDuct ™ MicroEndoscope and Accessories

Manufacturer Information:

Acueity, Inc.
15 Industrial Park East
Oxford, MA 01540

Contact: Shelley Trimm

Establishment Registration Number: 2436879

FDA Device Classification:

Standard Product Nomenclature:	Laparoscope & Accessories
Product Code:	78GCT
CFR Number:	876.500
Risk Class:	II
Classification Panel:	General & Plastic Surgery

Standard Product Nomenclature:	Biopsy Needle & Accessories
Product Code:	78FCG
CFR Number:	876.1075
Risk Class:	II
Classification Panel:	GU

Intended Use and Product Description:

The Viaduct will be labeled for the intended use of:

> This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or an incision.

The Acueity ViaDuct MicroEndoscope is a semi-rigid fiberscope with a single use sheath and a re-useable (reposable) microendoscope. The device is provided and labeled non-sterile. The microendoscope must be sterilized prior to use. (See instructions for cleaning and sterilization).

Substantial Equivalence:

Establishment of equivalence is based on similarities of intended use, design, and materials, physical characteristics and geometry between the ViaDuct MicroEndoscope and DOFI Microendoscope (K983527) and Solos Endoscope (K932987) among other marketed visualization products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2001

Ms. Mary Beth Fecteau
Quality and Regulatory Manager
Acueity, Inc.
15 Industrial Park East
Oxford, Massachusetts 01540

Re: K011189
Trade/Device Name: ViaDuct™ MicroEndoscope and Accessories
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: April 16, 2001
Received: April 18, 2001

Dear Ms. Fecteau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K011189

Device Name: **ViaDuct Microendoscope**

Indication for Use:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or an incision.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (YES) NO or Over-the-Counter Use Yes (No)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011189

(Division Sign-Off)

510(k) Number: